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ART UNIT PAPER NUMBER

DATE MAILED: 09/27/90

U.S. DEPARTMENT OF COMMERCE
BUREAU OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 5 July 1990 ☒ This action is made final.
A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474. 6. ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-15 are pending in the application.
- Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-15 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

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The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1,2 and 6 through 15 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al taken with Brown et al.

Anderson et al figure 1 on page 176 shows an arrangement for measuring hemoglobin in blood. The arrangement has a controllable source of monochromatic light (section 3.3, page 178) and a cuvette for holding a sample of whole, undiluted blood; see page 174 for a discussion of the use of such tests with whole undiluted/blood. The device of Anderson et al was used with an optical absorbance path through the sample of .011 cm, or 110 micrometers, which is in the instant disclosed range of 80 to 150 micrometers disclosed as being the range which minimizes the effect of light scattering. There is a light

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detector which is positioned to receive and detect light from the source of light forwardly scattered by the sample; the detector is positioned and has a light detecting area which minimizes the effect of length scattering by the sample.

The wavelengths used by Anderson et al, in the range from 500 to 620 nanometers, and in particular 505,520,530 and 560 nanometers (page 179) is virtually identical with the range disclosed on page 7 of the instant specification, which runs from 506 to 620 nanometers, which are disclosed as being those which minimize the effect of radiation scattering and maximize radiation absorbance of blood. Of the particular wavelengths disclosed on page 179 of the reference two (520 and 560 nanometers) are the same as specific wavelengths mentioned on page 7 of the instant specification, and a third (505 nonometers) differs from another instant disclosed wavelength (506 nonometers) by only one nanometer.

The use of such optical density measurements are known to be usable to calculate blood components; the Anderson et al reference makes reference to the use of such to calculate oxygen saturation (page 182, section 4.2. first sentence, for example). It would have been obvious to use measurements from such an instrument to calculate blood constituents because such use of optical absorbance for such calculations is known and such a use is at least suggested by the Anderson reference in its mention of

the use of the data in oxygen saturation measurement. Brown et al teaches it is known to use such measurements at different wavelengths to calculate several different constituents of blood. The use of the data obtained from the device of Anderson et al to calculate the concentrations of at least three constituents of blood would have been obvious because it is known, as shown by Brown et al. to use such data for such purposes.

While Anderson et al used a spectrophotometer to generate the particular wavelengths of interest other known methods of generating the desired wavelengths, such as a tunable laser, interference filters or the like would have been obvious because it is the provision of the particular wavelengths of interest, and not the means for providing them, which provides the data of interest.

Claims 3 through 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Anderson et al and Brown et al as applied to claim 1 above, and further in view of Shibata.

Anderson et al discusses the problem of light scatter, and uses a detector arrangement, with an integrating sphere, to capture substantially all of the light which passes through the sample in a generally forward direction. It is known that this same capturing of substantially all forwardly directed light can be achieved by using a large detector placed close to the sample; see figures 2A, 2B and 4 of Shibata et al. and column 3, lines 17

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through 27. The use of such a large close detector would have been obvious because it is a known alternative method for obtaining the same desired result and does not require the additional presence of an integrating sphere.

Remarks

The Information Disclosure Statement and references filed 7 July 1989 were considered during the preparation of the first office action; the file records indicate that a copy of the signed PTO-1449 was returned with the Office action mailed 3 April 1990. A copy of the signed PTO-1449 is included herewith.

While Anderson et al does not explicitly teach determining at least three constituents of blood, Anderson et al does relate the arrangement therein to "conventional spectrophotometric teachings" over a range of wavelengths used in the art for measurements of the constituents of blood. Thus Anderson et al. supports the suggestion to use that data - gathering arrangement to gather data at appropriate wavelengths to calculate three or more constituents of blood in the manner known in the art and illustrated by Brown et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the

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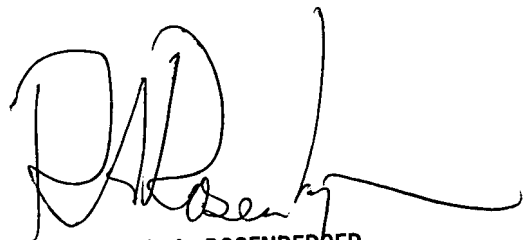
Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner R.A. Rosenberger whose telephone number is (703) 557-4347.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-3311.

Rosenberger/rk
September 19, 1990



RICHARD A. ROSENBERGER
EXAMINER
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